

## REMARKS

The Requirement mailed 25 October 2010, has been received and its contents carefully noted. By this amendment, claim 1 has been amended, claims 40-45 have been canceled, and claims 46-58 are newly added. Support may be found in the specification and the claims as originally filed. No statutory new matter has been added. Therefore, reconsideration and entry of the claims as amended is respectfully requested.

### Restriction Requirement

In the Requirement mailed 25 October 2010, the Examiner required a restriction as Examiner deemed that the inventions of Groups I through X do not relate to a single general inventive concept because they lacked the same or corresponding special technical features.

Applicants hereby elect to prosecute the claims of Invention II, claims 2, 4-5, 7-10, 12-14, 18, 21, 26-28 and 30-32, with traverse. Applicants have added claims 46-58. New claims 46-58 depend on the method claims of Invention II and therefore fall within the subject matter of Invention II and should be examined with the claims of Invention II. Applicants reserve the right to pursue any subject matter canceled as a result of this Requirement in a continuing application without prejudice or disclaimer.

Applicants respectfully submit that this election is with traverse as the claims, as amended, contained the following special technical feature “wherein in average 2-4 molecules of the part a) – c) above are linked to the anti Erb antibody”.

The conjugate according to the present invention containing in average 2-4 molecules of a) a tri-functional cross-linking moiety, b) an affinity ligand, and c) a cytotoxic agent, bound to one anti Erb antibody, has the main advantage of providing the possibility of increasing the dose or amount of the cytotoxic agent added to a human body in connection with cancer treatment compared to previously known methods.

It is known that the administration of a medical agent containing a cytotoxic agent bound to a tumor surface specific molecule, in this case an anti Erb antibody, results in a specific binding of a certain amount of the medical agent to the tumor surface, while the remaining amount of the non-bound medical agent remains for days or weeks in the blood circulation and exposes the body for undesired cytotoxic effects on healthy tissues and organs. For each kind of

cytotoxic agent a maximum dose thereof to be added to a patient has been established. In the prior art only one cytotoxic agent is known to be present per antibody in the medical agents administered to cancer patients.

However, according to the present invention, more than one, more precisely in average 2-4, cytotoxic agents per antibody in the conjugate, i.e. the medical agent, may be administrated. Thereby, a higher dose of the cytotoxic agent will be available close to the tumor surface, to which the antibody part of the conjugate binds, where the cytotoxic agents can exert their tumor killing effect.

Further, the presence of in average 2-4 affinity ligands, e.g. biotin, in addition to the in average 2-4 cytotoxic agents, in the conjugate facilitates and speeds up the extracorporeal removal of undesired remaining conjugates containing cytotoxic agents in the blood circulation. The adsorption rate of the extracorporeal filter, e.g. containing avidin, used for removal of said non-bound conjugates from the blood circulation is increased due to the increased amount of affinity ligands per conjugate, which thereby reduces the time period needed for the removal of the conjugates from the patient body, i.e. the undesired non-bound conjugates may be eliminated much quicker. This means that a higher total dose of cytotoxic agent in the medical agent may be administered to a cancer patient compared to prior art without any further negative influence for the body organs. This automatically also means that a higher dose of the inventive conjugate may be administered compared to the prior art conjugates.

To sum up, the increased dose of cytotoxic agent per antibody in the conjugate administered and the increased extracorporeal removal of non-bound conjugates from the patient body clearly improves the cancer treatment compared to previous known treatments. Another accompanying advantage of the inventive conjugate is that the unique structure of the conjugate makes it stable, both on its way to the tumor surface and when present in the blood circulation in the case it has not been bound to the tumor surface, which substantially reduces the risk for harmful effects on tissues and organs before said conjugates are extracorporeally eliminated from the patient body. Moreover, the inventive conjugate has a structure that does not negatively influence the binding properties, the biodistribution, and the biokinetics of the anti Erb antibody.

To conclude, none of the cited documents teaches or suggests the claimed conjugates and improved ways of cancer treatment, i.e. conjugates in which more than one part corresponding to

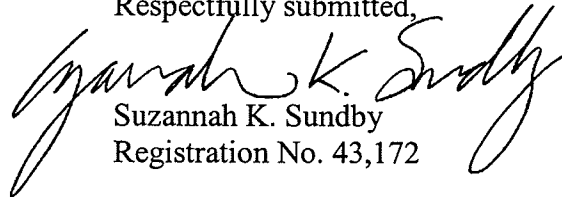
features a) – c) in claim 1 is bound to one anti Erb antibody. Therefore, Applicants respectfully request that the withdrawn subject matter be rejoined and examined.

### CONCLUSION

This election is made without prejudice to or disclaimer of the other claims or inventions disclosed. The right to file one or more divisional applications to the non-elected groups is respectfully reserved. Accordingly, reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. 1.136(a), and any fees required therefor are hereby authorized to be charged to **Deposit Account No. 024300, Attorney Docket No. 033972.011.**

Respectfully submitted,



Suzannah K. Sundby  
Registration No. 43,172

Date: 24 November 2010  
SMITH, GAMBRELL & RUSSELL, LLP  
1130 Connecticut Ave., NW, #1130  
Washington, D.C. 20036  
Telephone: (202) 263-4332  
Fax: (202) 263-4352  
ssundby@sgrlaw.com